REMARKS

Currently, claims 1-78 are pending. Claim 1 has been amended for the reasons discussed below. Applicants address each of the objections and rejections in the order in which they appear in the Action.

Applicants wish to thank the Examiner for the thorough and thoughtful review of the application and the prior art. Further, Applicants acknowledge the Examiner's indication that claims 16-18, 53 and 54 would be allowable if rewritten as independent claims, incorporating the features of the claims from which they depend.

A. Claims 1-5, 7-11, 39, 40, 70 and 78 Are Not Anticipated by EP 0469814A1 to Everett

Claims 1-5, 7-11, 39, 40, and 70 were rejected under 35 U.S.C. §102(b) as being anticipated by EP Patent No. 0 469 814 A1 to Everett (Everett). Applicants traverse this rejection.

In order for a reference to anticipate, it must teach all elements of the claimed invention assembled as in the claimed invention. As explained below, Everett does not teach every limitation of the claims in the manner set forth in the claims neither as they existed prior to this amendment nor as they exist after this amendment.

1. Claim 1 recites "plural elongate form medicament carriers, each carrier having multiple distinct medicament dose portions carried thereby, the medicament dose portions of each carrier containing a medicament active, or a mixture of medicament actives, which is different from that in the medicament dose portions of the other carrier(s)." For brevity only, this requirement for the carriers to each contain a medicament active, or a mixture of medicament actives, which is different from that in the other carriers, is hereinafter referred to as each carrier having "different actives." Everett does not teach this element and, therefore, cannot anticipate.

Everett discloses a device which sequentially accesses individual doses of powder medicament from a flat strip 38, which is housed in a first compartment 19. Everett also describes a "fresh medicament strip 38a" which is contained in a separate storage area in

the device. The "fresh medicament strip 38a…can be placed in operating position in compartment 19 when the strip 38 is used up." (Col. 4, lines 39-41).

One of ordinary skill would recognize this description as indicating that the "fresh medicament strip 38a" is a replacement strip, as it is described as "fresh" and the original strip 38 is "used up." Moreover, it would be understood that this would mean that the "fresh" strip has the same active compound as the "used up" strip, due to the plain meaning of these phrases. Nothing in the Everett disclosure indicates a contrary meaning, and to somehow to imply this would ignore how one of ordinary skill would view this text.

Moreover, such a reading would ignore practice in the pharmaceutical field. Government authorities regulating drug sales would require the device to deliver the indicated dosage of a specified drug. Separate prescriptions would be required for separate medications. If Everett intended this to be read in the manner apparently adopted by the Examiner, the description would specifically describe the strips 38 and 38a as being filled with different actives. It does not. In the absence of a specific disclosure, Everett fails to specifically describe either explicitly or inherently (there being no finding that the reference must result in such a reading) that one carrier strip contains a different medicament active than the other "fresh" carrier strip.

For this reason, Applicants respectfully request that this rejection be withdrawn.

2. Claim 1 also recites that the release of the claimed device operate by "releasing in combination a distinct medicament dose portion from each of the plural medicament carriers on receipt thereof by said at least one receiving station."

Everett describes that strip 38 is contained in a first compartment 19, and that the fresh strip 38a is contained in a second compartment 20. While compartment 19 contains the working mechanism of the device, such as the indexing sprocket 26 that feeds the strip 38 into alignment with the aperture 34, where the blister base struck by the plunger or hammer 31, compartment 20 where the replacement strip is located has no working pieces. This is because the compartment only serves as a storage area to house the "fresh strip" 38a.

As such, the plain meaning of Everett indicates that the doses on the strips 38 and 38a are not released "in combination." Instead the fresh strip is removed from the storage compartment 20 and loaded into the active compartment 19, only after the initial strip 38 is "used up."

As Everett fails to disclose releasing distinct medicament dose from each of the plural carriers "in combination" it does not meet the all limitations standard of anticipation.

For this additional reason, the Examiner's position on anticipation under §102(b) is unsustainable and it is requested that it be withdrawn.

3. Claim 1 has been amended to again emphasize that the claimed dispenser comprises "a dispensing mechanism which is adapted to operate, upon each actuation of the dispenser, to act upon each of the plural medicament carriers together to dispense a single distinct medicament dose portion carried by each of said plural medicament carriers."

This amendment is made to assist the Examiner in a proper understanding of the invention as previously claimed.

As explained above, Everett only teaches dispensing a single dose portion on a single strip per actuation. The fresh strip 38a is only loaded into the "active" compartment 19 after first strip 38 is "used up." This is fundamentally different from the claimed dispenser that dispenses the different actives from each of the plural carriers together, in combination.

Everett does not disclose anything regarding dispensing from a plurality of carriers together.

For this further reason, the rejection under 35 USC §102(b) over Everett is incorrect.

4. Claim 1 also recites "an outlet, positioned to be in communication with the combination of distinct medicament dose portions releasable by said release and through which a user is able to access said combination of distinct medicament dose portions."

Everett does not describe the dose portions of strip 38 and strip 38a being positioned such they are struck by hammer or plunger 31 at the same time, let alone having an outlet "positioned to be in communication with the combination of distinct medicament dose portions releasable by said release and through which a user is able to access said combination of distinct medicament dose portions" as in claim 1.

In fact, strip 38a is housed in a completely separate compartment 20 when a dose portion of the active strip 38 is being struck by the hammer or plunger. As such, Everett does not describe an opening in communication with the "combination of distinct medicament dose portions."

Thus, for the reasons highlighted in numbered paragraphs 1 through 4 above, the rejection of claim 1 under 35 USC §102(b) is unfounded. As claim 1 is not anticipated by Everett, as a matter of law, none of the claims depending from claim 1 can be anticipated.

The Examiner makes no detailed finding relation to claims 39, 40, 70 or 78 in the discussion of the §102 rejection. That said, Everett does not disclose a device allowing "simultaneous inhalation by the user of the medicament dose portions dispenser from the medicament carriers by the dispensing mechanism on actuation of the device" as recited in claim 78, nor could Everett achieve such a feat as only a single carrier is employed at any one time. Simultaneous delivery from dose portions of strips 38 and 38a is neither described nor suggested in Everett.

In light of the above, it is requested that the rejection of claims 1-5, 7-11, 39, 40, 70 and 78 based on anticipation be withdrawn. The Examiner's comments regarding claims 3, 4, 5, 8-11 are premised on the misunderstanding of the teachings of Everett, and on the language of claim 1. Applicants have not discussed each and every claim in turn, as it is unnecessary in light of the above. However, this silence should not be viewed as an acceptance of the Examiner's position on those additional points. Applicants reserve the right to address such matters in the future, should they be deemed pertinent to the prosecution of a given claimed invention.

B. Claims 6, 12-25, 19-31, 38, 41-49, 52, 56-69 and 71-78 Are Not Obvious under 35 USC §103(a)

Claims 6, 12-15, 19-31, 38, 41-49, 52, 56-69, and 71-78 were rejected under 35 U.S.C. §103(a) as being unpatentable over Everett in view of U.S. Patent No. 5,873,360 (Davies). This assertion is also respectfully traversed.

The Examiner's position as to obviousness is premised on Everett describing each limitation of claim 1. As described above, Everett does not disclose each and every element of claim 1. For this reason alone, the rejections made under §103 must fail.

Everett does not disclose or suggest a dispenser having plural medicament carriers containing different actives. Nor does Everett disclose a device in which such different actives from different carriers are dispensed together and released in combination.

Davies does not remedy the shortcomings of Everett.

Both describe devices which release a single dose from just a single strip at any given time. Neither mentions anything about multiple strips containing different actives in the same device. Nothing in either suggests that different actives in different strips be dispensed together. To the extent that these references mention additional strips for use in the described devices, it is always in reference to replacement strips that are loaded only after an old strip is "used up" (*see,* Everett col. 4, lines 39-41 and Davies col. 3, lines 59-67). As such, neither claim 1 nor any claim dependent thereon is obvious in light of Everett in view of Davies.

1. Claim 6 is not obvious in light of the teachings of Everett in view of Davies.

Addressing the Examiner's findings concerning claim 6, Applicants respectfully assert that the position taken by the Examiner to employ a peelable blister taught by Davies in the Everett "burst" access device is a mere unsubstantiated conclusion based only on hindsight, rather than being based on the knowledge of those in the art.

The Examiner states that one of ordinary skill would have been motivated to employ a peelable strip in Everett's "burst" device, as "the dispenser would be operable with different types."

Assuming that the "different types" refers to different types *of blister strips*, it is respectfully asserted that this conclusion ignores the very premise on which these two very different systems operate. An understanding of each dictates a contrary conclusion.

Davies describes a hermetically sealed blister (col. 1, lines 47-51), wherein the lid layer remains intact as it is peeled from the base strip in order to expose the contents of the blister (col. 4, lines 23-26). Upon peeling the lid from the base sheet, the lid sheet is wound up on an uptake wheel 14. To allow the peeling to occur, the seal between the lid and base sheets must "fail" without the lid layer being sheared. Lid integrity after peeling is important to allow the lid layer to be wound by the uptake wheel (14), which in turn allows the lid section of the next dose on the carrier strip to be peeled from the base sheet.

In the Davies device, if the lid layer tore while the seal remained intact, the dose in the blister may not be exposed (completely or at all), and moreover, the lid foil would not continue to be wound on the uptake wheel 14, which means the unexposed blister's down-strip from the tear would not be exposed upon further actuation. As this device is used, for example, to deliver asthma rescue medication, such a catastrophic failure could result in an unaddressed asthma attack and possible death of a patient using the device.

Everett, in contrast to Davies, operates on a completely different approach. As described in col. 4, lines 5-8 of Everett, the lid is ruptured by the compressive force of a plunger or hammer 31 striking the underside of the blister receptacle. This compression of the blister causes the pressure inside the blister to increase, which results in the foil overlying the blister to rupture. By rupturing, the powder is forcing through the tear in the lid, through aperture 34, and into compartment 21 from which it passes out of the device and is inhaled. Thus, the blister content in Everett must be forced through the lid foil in order to operate correctly.

If as the Examiner suggests, a blister strip which was intended to be peeled was placed in the Everett device, compression of the blister back by the plunger hammer would

lead to an increase in pressure in the interior of the pack. This increased pressure would cause the peelable blister to give way where it was intended to open, *i.e.*, along the seal, rather than through the foil lid layer. A breach of blister integrity along the seal would drive the powder sideways, between the base and foil layers, causing the contents of the blister to be dispersed laterally into the interior of chamber 19, rather than through aperture 34 and into inhalation compartment 21.

Thus by employing a strip intended to be peeled in an Everett-type device, it invites device malfunction, with the same potentially catastrophic effects to a patient as is described above. It is respectfully asserted that one would not be motivated to use a Davies type strip in an Everett type device.

If however, the Examiner's statement that one of ordinary skill would have been motivated to employ a peelable strip in Everett's "burst" device, as "the dispenser would be operable with different types [*of mechanisms for accessing the contents of the blister pocket*], then applicant must assert that the inclusion of a peeling mechanism in Everett would remove the very invention the system describes—the accessing of blister contents by compression with a hammer and the bursting of a lid layer, and would be such a radical departure from Everett, that one would *not* be motivated to take such an action.

2. Additional points.

Davies depicts a medicament dispenser with a single carrier strip 401. This single has multiple blisters. It does not describe plural blister strips, as indicated on page 4, lines 2 and 3 of last paragraph of the Office Action.

As explained in Davies, col. 7, lines 7-9, this single strip has multiple distinct pockets 402 defined in a base sheet 403, which are covered by a lid sheet 404. Davies does not describe a device employing plural carrier sheets, and the term "plural carrier sheets" cannot be interpreted to mean a single sheet with multiple distinct medicament dose portions.

Applicants have not addressed each point raised by the Examiner with respect to the dependent claims, as in light of the discussion above these points were not necessary to address the Examiner's failure to establish a *prima facie* case of obviousness based on

Everett in view of Davies. Applicants' silence should not be taken as an acceptance of the Examiner's positions. Applicants merely reserve the right to address these points in the future, should the need arise.

Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Everett, alone or in combination with Davies, fails to disclose each limitation of claim 1, or any of the claims dependent thereon. By their dependence on claim 1 and for the additional reasons mentioned or inferred herein, remaining claims 2-78 are both novel and inventive.

It is respectfully submitted that the present application is in condition for allowance. An early consideration and Notice of Allowance are earnestly solicited.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or to credit any overpayment, particularly including any fees required under 37 CFR §1.16 or §1.17, and any necessary extension of time fees, to Deposit Account No. 07-1392.

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